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SUMMARY OF SAFETY AND EFFECTIVENESS

K002483

1. Device Name:	Magnetic Resonance Imaging Accessory
2. Proprietary Name:	Power 5000 General Purpose Coil
3. Classification:	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc., 1515 Danner Drive Aurora, Ohio 44202, USA Telephone: 330-562-1000; Fax: 330-562-1422.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The Power 5000 General Purpose Coil is a receive-only single channel RF coil, used for obtaining diagnostic images of a variety of anatomical regions in Magnetic Resonance Imaging Systems. A variety of positioning options allows for imaging of various joints in articulated positions. The indications for use are the same as for standard MR Imaging. The Power 5000 General Purpose Coil is designed for use with the GE MFO 0.35Tesla MRI scanner manufactured by GE Medical Systems, Inc.
8. Device Description:	The Power 5000 General Purpose Coil is a single channel receive-only RF coil. The coil consists of a single 6-inch diameter loop. The coil elements and associated circuitry is enclosed in a semi flexible housing. The semi-flexible housing allows the coil to wrap around the area of interest for imaging small anatomic regions.

K002483

9. Safety and Effectiveness

Power 5000 General Purpose Coil Product Features	Comparison to Predicate or other 510(k) cleared products
Intended Use Imaging a variety of anatomical features including small joints and extremities.	-Similar to the Multipurpose Flexible Coil manufactured by Marconi Medical Systems, Inc. (K944469)
Indications for Use Identical to routine MRI imaging	-Similar to the Multipurpose Flexible Coil manufactured by Marconi Medical Systems, Inc. (K944469)
Coil Material Royalite R59™ ABS Plastic Hapflex™ 581FR Vinyl coated Polyurethane Foam	-Similar to Magna 5000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc (K994345) -Similar to Insight Plus 9000 Torso and Pelvis Coil manufactured by USA Instruments, Inc. (K001209)
Coil Design Single channel receive-only design	-Similar to the Multipurpose Flexible Coil manufactured by Marconi Medical Systems, Inc. (K944469)
Decoupling RF Chokes with Switching Diodes	-Similar to the Multipurpose Flexible Coil manufactured by Marconi Medical Systems, Inc. (K944469)
Prevention of RF Burns Does not transmit RF Power, Decoupling isolates the coil elements from RF fields during RF transmission, Coil elements and circuitry are enclosed in a non-conductive housing.	-Similar to the Multipurpose Flexible Coil manufactured by Marconi Medical Systems, Inc. (K944469)
Radio Frequency Absorption Coil is a receive only coil and does not transmit RF power	-Similar to the Multipurpose Flexible Coil manufactured by Marconi Medical Systems, Inc. (K944469)
Formation of Resonant Loops Decoupling isolates coil elements from RF fields during RF transmission, Length of cable and stiffness does not permit looping	-Similar to the Multipurpose Flexible Coil manufactured by Marconi Medical Systems, Inc. (K944469)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2000

Rony Thomas
Vice President of Marketing and Programs
USA Instruments, Inc.
1515 Danner Drive
Aurora, Ohio 44202

Re: K002483
POWER 5000 General Purpose Coil
Dated: August 9, 2000
Received: August 14, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Mr. Thomas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002483

Device Name: Power 5000 General Purpose Coil

Indications for Use: The Power 5000 General Purpose Coil is designed to provide Magnetic Resonance Images of numerous anatomical features such as the shoulder, neck, upper and lower extremities and small joints. The Power 5000 General Purpose Coil is designed for use with the GE MFO 0.35Tesla scanner.

Anatomic Regions:	Upper and Lower Extremities, Small Joints, Neck, and Shoulder.
Nuclei Excited:	Hydrogen

The indications for use are the same as for standard imaging:

The GE MFO 0.35T system is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002483